REMARKS

Claims 1-6, 8, 10, 15-23 and 25-35 are pending in the application. Claims 1, 25 and 26 are currently amended. Claims 2-6, 8, 10, 15-23 and 27-35 were previously presented; claims 15-23 and 27-35 were previously presented as new claims added in a preliminary amendment; claims 7, 9, 11-14 and 24 were cancelled. A copy of the claims now pending in the application in accord with 37 CFR 1.121, as revised, has been provided.

No new matter has been introduced by virtue of the amendments made herein. Accordingly, applicants respectfully request their entry. In view of the amendments made herein and the remarks below, applicants respectfully request reconsideration and withdrawal of the rejection set forth in the May 21, 2004 office action.

Specification

The Examiner required correction of the paragraph that was added at page 7, after line 14. The Examiner objected to the phrase "R^5 and R^6 are as defined in claim 2". Without prejudice and in the interests of facilitating prosecution, applicants have amended this paragraph to recite "R^5 and R^6 are defined as in formula I above", and respectfully request the Examiner to withdraw the objection.

Rejection under 35 USC § 112, first paragraph

The Examiner rejected claims 1-6, 8, 10 and 15-35 under 35 USC § 112, first paragraph ""because the specification, ..., does not reasonably provide enablement for the complex compositions of formula I as claimed herein." However, the Examiner concedes the specification is "enabling for the pharmaceutical compositions of the compounds of formula I...."

Applicants submit that the second paragraph of the instant specification recites "The compounds of this invention may also be used in combination..." with the additional active ingredients cited by the Examiner. Applicants submit that the specific compounds that are embraced by the cited classes is common knowledge to those skilled in the art. The Examiner concedes the specification is "enabling for the pharmaceutical compositions of the compounds of formula I....". Applicants respectfully submit the specification is also enabling to those skilled in the art seeking to formulate the compounds of formula I into the pharmaceutical compositions that include the classes of active ingredients recited in claim 1.

Applicants submit that claims 1-6, 8, 10 and 15-35 are patentable under 35 USC § 112, first paragraph, and respectfully request the Examiner to withdraw the rejection.

The Examiner also rejected claims 15 and 16 under 35 USC § 112, first paragraph, as failing to comply with the written description requirement. The Examiner asserts that the species

"2-fluoro-N-(4-hydroxy)[sic]-10-aza-tricyclo[6.3.1.$0^{2,7}$]dodeca-2(7),3,5-trien-5-yl)-benzamide" in claim 15 and 4,5-bistrifluoromethyl-10-aza-tricyclo[6.3.1.$0^{2,7}$]dodeca-2(7),3,5-triene in claim 16 are not described in the specification.

Applicant submits that 2-fluoro-N-(4-hydroxy-10-aza-tricyclo[6.3.1.$0^{2,7}$]dodeca-2(7),3,5-trien-5-yl)-benzamide the compound recited in claim 15 may be found in the specification in the "Summary of The Invention" section as the third species in the list of "Examples of specific compounds of the formula I."

Applicant further submits that 4,5-bistrifluoromethyl-10-aza-tricyclo[6.3.1.$0^{2,7}$]dodeca-2(7),3,5-triene recited in claim 16 may be found in the specification in the "Summary of The Invention" section as the last species in the list of "Other embodiments compounds of the invention include...."

Applicants submit that claims 15 and 16 are patentable under 35 USC § 112, first paragraph, and respectfully request the Examiner to withdraw the rejection.

Rejection under 35 USC § 112, second paragraph

The Examiner rejected claims 1, 8, 10 and 15-35 under 35 USC § 112, second paragraph, for indefiniteness. The reasons for rejection cited by the Examiner were:

a) The recitation in claim 1 (and claims dependent thereon) of the phrase "aryl and heteroaryl groups may optionally be substituted with one or more substituents, preferably from zero to two substituents," as rendering the claim indefinite. Without prejudice and in the interests of facilitating prosecution, applicants have amended claim 1 by deletion of the phrase "preferably from zero to two substituents".

b) Insufficient antecedent basis for the recitation of "and pharmaceutically acceptable salts thereof" in claims 15-35. Applicants note that claims 15-17 recite the foregoing phrase; claims 18-23 and 27-35 recite "or a pharmaceutically acceptable salt thereof" but it is not recited in either form by claims 24-26. Without prejudice and in the interests of facilitating prosecution applicants have amended claim 1 to recite the phrase "or, a pharmaceutically acceptable salt thereof" which was inadvertently omitted from the preliminary amendment to claim 1. Support for this phrase is found throughout the specification, specifically in the "Summary of the Invention" section. Applicants submit that as a result of the foregoing amendment, the use of the phrases "and pharmaceutically acceptable salts thereof" in claims 15-17 "or a pharmaceutically acceptable salt thereof" in claims 18-23 and 27-35 has sufficient antecedent basis.

c) Use of "...the antidepressant..." in claim 24. Without prejudice and in the interests of facilitating prosecution, applicants have cancelled claim 24 as a result of amendment to claim 1 deleting "antidepressant," as discussed below.

d) In claim 25, recital of "the neurotrophic factor is NGF". Without prejudice and in the interests of facilitating prosecution, applicants have amended claim 25 to be dependent on claim 1 by addition of the phrase "according to claim 1."

e) In claim 25, lack of a period to end the claim. Without prejudice and in the interests of facilitating prosecution, applicants have amended claim 25 by addition of a period --.-- at the end the claim.

f) In claim 26, recital of "the agent that slows or arrests Alzheimer's disease." Without prejudice and in the interests of facilitating prosecution, applicants have amended claim 26 to be dependent on claim 1 by addition of the phrase "according to claim 1".

In addition, without prejudice and in the interests of facilitating prosecution, applicants have amended claim 1 by deleting the "s" in the term "neurotrophic factors" so that currently amended claim 1 recites "neurotrophic factor" and by inserting the word "an" before "estrogen-like".

Applicants submit that currently amended claims 1, 25 and 26 and previously presented claims 8, 10, 15-23 and 27-35 are patentable under 35 USC § 112, second paragraph, and respectfully request the Examiner to withdraw the rejection.

Double Patenting

The Examiner provisionally rejected claims 1-6, 8, 10, 15-19, 22, 24-27 and 30-35 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-34 of copending Application No. 10/348,381. The Examiner concedes that the conflicting claims are not identical but states that "they are not patentably distinct from each other because the compositions and method of use of the compounds of formula I of the instant invention are embraced by the compositions and method of use of the compounds of the formula where R^1 is hydrogen or ethanone, and R^2 and/or R^3 are methyl, fluoro, trifluoromethyl, nitro, chloro, cyano, hydroxyl, etc."

Applicants submit that instant currently amended claims 1-6 are specifically directed to pharmaceutical compositions comprising a compound of formula (I) "and pharmaceutically acceptable salts thereof ... and a compound that is selected from a muscarinic agonist, a neurotrophic factor, an agent that slows or arrests Alzheimer's disease, an amyloid aggregation inhibitor, a secretase inhibitor, a tau kinase inhibitor, a neuronal antiinflammatory agent and estrogen-like therapeutic agent", while instant claims 8, 10, 15-19, 22, 24-27 and 30-35 are directed to methods of treating conditions and disorders utilizing the pharmaceutical composition of claim 1 and pharmaceutical compositions according to claim 1 that recite specific species while claims 1-34 of copending Application No. 10/348,381 recite pharmaceutical compositions and methods of use based on a combination of "a nicotine receptor partial agonist or pharmaceutically acceptable salt thereof" and "*an analgesic agent or pharmaceutically acceptable salt thereof*".

Applicants submit instant claims 1-6, 8, 10, 15-19, 22, 24-27 and 30-35 do not recite "*an analgesic agent or pharmaceutically acceptable salt thereof*" and are patentably distinct from claims 1-34 of copending Application No. 10/348,381 under the judicially created doctrine of obviousness-type double patenting, and therefore, respectfully request the Examiner to withdraw the provisional rejection.

Claims 1-6, 8, 10, 15-19, 22, 24-28 and 30-35 were also provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-18 of copending Application No. 10/348,399. The Examiner concedes that the conflicting claims are not identical but states that they are not patentably distinct from each other because the compositions and method of use of the compounds of formula I of the instant invention are embraced by the compositions and method of use of the compounds of the formula where R^1 is hydrogen or ethanone, and R^2 and/or R^3 are methyl, fluoro, trifluoromethyl, nitro, chloro, cyano, hydroxyl, etc.

Without prejudice and in the interests of facilitating prosecution, applicants have amended claim 1 by deletion of the term "an antidepressant," and have cancelled dependent claim 24 directed to the type of antidepressant. Applicants submit that instant currently amended claims 1-6, 8, 10, 15-19, 22, 25-28 and 30-35 are specifically directed to the pharmaceutical compositions and methods as described above that do not include an antidepressant while claims 1-18 of copending Application No. 10/348,399 recite pharmaceutical compositions and methods of use based on a combination of "a nicotine receptor partial agonist *and an anti-depressant or anxiolytic agent*". Applicants submit that the pharmaceutical compositions and methods of use of instant claims 1-6, 8, 10, 15-19, 22, 25-28 and 30-35, as currently amended, are patentably distinct from those of claims 1-18 of copending Application No. 10/348,399 under the judicially created doctrine of obviousness-type double patenting, and therefore, respectfully request the Examiner to withdraw the provisional rejection.

The Examiner also provisionally rejected claims 1, 3-6, 8, 10, and 15-26 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 7-10 of copending Application No. 10/075,843. The Examiner concedes that the conflicting claims are not identical but states that they are not patentably distinct from each other because the compositions and method of use of the compounds of formula I of the instant invention are embraced by the compositions and method of use of the compounds of formula (I) where R^1 is hydrogen, $(C_1\text{-}C_6)$alkyl, unconjugated $(C_3\text{-}C_6)$alkenyl, $XC(=O)R^{13}$, benzyl or $-CH_2CH_2\text{-}O\text{-}(C_1\text{-}C_4)$alkyl, and R^2 and R^3 are hydrogen, $(C_2\text{-}C_6)$alkenyl, $(C_2\text{-}C_6)$alkynyl, hydroxyl, nitro, amino, halo, cyano, etc.

Applicants submit that claim 24 has been cancelled as noted above, and instant currently amended claims 1, 3-6, 8, 10, and 15-23 and 25-26 are specifically directed to the pharmaceutical compositions and methods as described above that rely on a combination of the

instant compound of claim I and another active ingredient, as set forth herein, while the pharmaceutical compositions and methods recited in claims 7-10 of copending application No. 10/075,843 do not specify any active ingredient apart from the compound of claim 1 as defined therein. Applicants submit that the pharmaceutical compositions and methods of use of instant claims 1, 3-6, 8, 10, and 15-23 and 25-26 as currently amended, are therefore patentably distinct from those of claims 7-10 of copending Application No. 10/075,843 under the judicially created doctrine of obviousness-type double patenting, and respectfully request the Examiner to withdraw the provisional rejection.

The Examiner rejected claims 1, 3, 8, 10, and 24-26 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-3 of U.S. Patent No. 6,605,610. The Examiner concedes that the conflicting claims are not identical but states that they are not patentably distinct from each other because the open claim language of the composition claims of U.S. '610, embraces the compositions of the instant invention with the additional active ingredients."

Applicants submit that claim 24 has been cancelled as described above. Applicants further submit that claims 1-3 of U.S. '610 are method claims, and do not refer to the pharmaceutical composition of instant claims 1, 3, 25 and 26 that specifically includes "...a compound that is selected from a muscarinic agonist, a neurotrophic factor, an agent that slows or arrests Alzheimer's disease, an amyloid aggregation inhibitor, a secretase inhibitor, a tau kinase inhibitor, a neuronal antiinflammatory agent and estrogen-like therapeutic agent" as recited in instant claim 1 as currently amended. Applicants submit instant claims 1, 3, 25 and 26 are patentably distinct from claims 1-3 of U.S. Patent 6,605,610 as they are directed to other subject matter not recited or suggested in the cited claims, and therefore, are patentable under the judicially created doctrine of obviousness-type double patenting. Accordingly, applicants respectfully request the Examiner to withdraw the rejection of claims 1, 3, 25 and 26 under the aforementioned judicially created doctrine.

Applicants still further submit that instant claims 8 and 10 recite methods that use the pharmaceutical composition of instant claim 1 that specifically includes "a compound that is selected from a muscarinic agonist, a neurotrophic factor, an agent that slows or arrests Alzheimer's disease, an amyloid aggregation inhibitor, a secretase inhibitor, a tau kinase inhibitor, a neuronal antiinflammatory agent and estrogen-like therapeutic agent" while method claims 1-3 of U.S. Patent 6,605,610 do not recite or suggest use of a pharmaceutical composition containing such compounds. Applicants submit instant claims 8 and 10 are therefore patentably distinct from claims 1-3 of U.S. Patent 6,605,610, and therefore patentable under the judicially created doctrine of obviousness-type double patenting, and respectfully request the Examiner to withdraw the rejection under the aforementioned judicially created doctrine.

The Examiner rejected claims 1-6, 8, 10, and 24-35 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 12-14 of U.S. Patent No. 6,410,550. The Examiner concedes that the conflicting claims are not identical but states that they are not patentably distinct from each other because the open claim language of the composition claims of U.S. '550, embraces the compositions of the instant invention with the additional active ingredients.

Applicants submit that claim 24 has been cancelled as noted above. Applicants further submit that claim 12 of U.S. Patent 6,410,550, directed to a pharmaceutical composition, does not recite or suggest a pharmaceutical composition that specifically includes "a compound that is selected from a muscarinic agonist, a neurotrophic factor, an agent that slows or arrests Alzheimer's disease, an amyloid aggregation inhibitor, a secretase inhibitor, a tau kinase inhibitor, a neuronal antiinflammatory agent and estrogen-like therapeutic agent" as recited in instant claim 1 and instant dependent claims 2-6 and 25-35, as currently amended, directed to pharmaceutical compositions.

Applicants further submit that claims 13 and 14 of U.S. Patent 6,410,550 are directed to other matter than instant claims 1-6 and 25-35 as they recite a method that uses "an amount of a compound according to claim 1" therein, and not a pharmaceutical composition, let alone a pharmaceutical composition that specifically includes "a compound that is selected from a muscarinic agonist, a neurotrophic factor, an agent that slows or arrests Alzheimer's disease, an amyloid aggregation inhibitor, a secretase inhibitor, a tau kinase inhibitor, a neuronal antiinflammatory agent and estrogen-like therapeutic agent".

Applicants still further submit that instant claims 8 and 10 recite methods that use the pharmaceutical composition of instant claim 1 that specifically includes "a compound that is selected from a muscarinic agonist, a neurotrophic factor, an agent that slows or arrests Alzheimer's disease, an amyloid aggregation inhibitor, a secretase inhibitor, a tau kinase inhibitor, a neuronal antiinflammatory agent and estrogen-like therapeutic agent" while claim 12 of U.S. Patent 6,410,550 is not a method claim but is directed to a pharmaceutical composition that does not recite or suggest use of such compounds.

Applicants further submit that the methods recited in claims 13-14 of U.S. Patent 6,410,550 employ "an amount of a compound according to claim 1" but do not recite or suggest "a compound that is selected from a muscarinic agonist, a neurotrophic factor, an agent that slows or arrests Alzheimer's disease, an amyloid aggregation inhibitor, a secretase inhibitor, a tau kinase inhibitor, a neuronal antiinflammatory agent and estrogen-like therapeutic agent" as is included in instant dependent method claims 8 and 10.

Applicants submit instant claims 1-6, 8, 10, and 25-35 are patentably distinct from claims 12-14 of U.S. Patent 6,410,550, and therefore patentable under the judicially created doctrine of

obviousness-type double patenting and respectfully request the Examiner to withdraw the rejection under the aforementioned judicially created doctrine.

In view of the amendments set forth herein and remarks above, applicants respectfully submit that the pending claims are fully allowable, and solicit the issuance of a notice to such effect. If a telephone interview is deemed to be helpful to expedite the prosecution of the subject application, the Examiner is invited to contact applicants' undersigned attorney at the telephone number provided.

The Commissioner is hereby authorized to charge any fees required under 37 C.F.R. §§1.16 and 1.17 or to credit any overpayment to Deposit Account No. 16-1445.

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